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NARKOMED 6000
TECHNICAL SERVICE BULLETIN # 6016

Product: Narkomed 6000

Date: October 28, 2002

Status: Mandatory Corrective Action

Re: Condor Power Supply - Recall

Reference Doc: IS# 02-093, ECN # 02-0662

Reason/ Rational: Implementation of design changes to reduce the possibility of a short circuit between the metal can of a capacitor and traces on a printed circuit board in the power supply. This action applies only to the serial numbers of Devices Affected listed below.

Solution/ Procedure: All affected Narkomed 6000's require the current power supply to be exchanged. Replacement supplies issued will be either p/n 4114431 as identified by the absence of a shroud surrounding the circuit breakers or a modified p/n 4116260 as identified by a shroud surrounding the circuit breakers and also containing rework label IS# 02-093 near the shroud or Rev H indicated on the power supply serial number label, (located near the 24V System (J6) connector; refer to Figure 1).

Dräger Medical, Inc. has established an aggressive replacement schedule and will contact the selected Authorized Service provider to arrange for this exchange. The power supply exchange must be completed within 3 business days from receipt of the outbound power supply shipment. The exchanged supply must be shipped to Draeger Medical on or before the 4th business day.

The outbound power supply box will contain the following:

- Pre-paid Fed-X Air Bill
- Formatted Returned Materials Authorization, (RMA)
- Blank Urgent Medical Device Correction form

Refer to the Narkomed 6000 Technical Service Manual, Section 4.19 for specific replacement instructions. During the exchange an Urgent Medical Device Correction form must be filled out in its entirety then placed in the return power supply's shipping carton.

If for any reason the power supply exchange can not be completed within the required time frame, you must ship the same power supply that you received on or before the 4th business day. Immediately notify Ken Horsfield at 800-543-5047 ext. 2561 and provide documentation in writing about the specific events that have occurred and you must include the name and phone number of the hospital personnel that were contacted. Forward this information to horsfieldk@nad.com. You must also inform the customer that we must re-schedule this exchange between 12/23/02-12/31/02.

DrägerService
3122 Commerce Drive
Telford, PA 18969
Tel: (215) 721-5402
(800) 543-5047
Fax: (215) 721-5784
Web: www.draegermed.com
DrägerService is a division of

Devices affected: Narkomed 6000's S/N xxxx - xxxxx. A machine consignee listing will be provided to each Distributor Service Manager and DMI, Regional Service Manager. A dispatch will also be created for affected devices within direct Dräger Medical Inc. locations. The dispatch will contain a request install date that correlates to the business day after the power supply is shipped.

Timing/ When: The affected power supply must be returned within 4-days from the date the power supply is received by the service provider. Target is to update all affected units within 8 weeks and no later then December 31st 2002.

Costs: Not applicable. Parts will be provided at no charge and shipping charges will be charged to Draeger Medical's Federal Express account.

Ordering Info/Parts: Not applicable, except for selected Authorized Service providers that require a purchase order for shipment tracking purposes.

Distribution: Draeger Medical Inc. USA – FieldService Department; Education Department, Customer Service Department, Affected DMI Distributors

Figure 1 – Power Supply Part Number Label

If you have any questions, please contact Technical Support by phone at 1-800-543-5047, by fax at 1-215-721-5789 or by E-mail at techsupport@draegermed.com

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URGENT MEDICAL DEVICE FIELD CORRECTION REPORT
NM6K POWER SUPPLY

After each power supply exchange is completed the account demographics, machine's serial number, power supply serial number removed, power supply serial number installed shall be entered on the report. A Technician signature, ID# and date are also required on each report. This form shall be completely filled out and placed in the return power supply's shipping carton.

Hospital Name: _____

Street Address: _____

City & State: _____

Zip Code: _____

Machine Serial Number: _____

Removed; Power Supply Part Number: _____

Removed; Power Supply Serial Number: _____

Installed; Power Supply Part Number: _____

Installed; Power Supply Serial Number: _____

Installed; Power Supply Revision or IS#: _____

TECHNICAN: **I.D. #** **DATE:**

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